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April 27, 2021

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US
Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of the April 28, 2021 Discovery
Hearing and Case Management Conference.

1. Plaintiffs' Request for Baohua Chen Custodial File

Baohua Chen is the Founder and Chairman of ZHP, and the CEO of Shanghai Syncores
(the wholly owned research entity that developed the ill-fated zinc chloride process for the
manufacture of valsartan in 2011). On December 18, 2019, Judge Schneider denied Plaintiffs'
request for Mr. Chen's inclusion as a custodian for purposes of a custodial production. However,

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the Court left this issue open: “I could be proven wrong in the future. If there is evidence in that regard, so be it.” ([12/18/2019 Tr. 24:14-15](#)). The Court added:

I'll make it clear. The Court is not ruling at this time whether or not Mr. Chen is an appropriate deponent. That's a completely different evaluation that the Court has to consider at the relevant time. If defendant [sic] wants to depose Mr. Chen, we'll deal with the issue at that point. But in no way, shape, or form should the Court's ruling as to whether or not Mr. Chen is an appropriate custodian be deemed as a ruling as to whether or not he may be deposed in the case.

(*Id.* at 24:20-25:2). Since that time, Plaintiffs prevailed, and Judge Schneider ruled that Baohua Chen was a proper deponent and the deposition was ordered and scheduled.¹ ([ECF 704](#)). Judge Schneider specifically explained that “with regard to Mr. Chen[,] **I'm not that sympathetic to the apex argument** for this reason, because it appears that Mr. Chen had responsible positions before he became, you know, the top of the food chain, so to speak. So **I don't think it's, you know, completely correct to say he's an apex witness**, because a lot of the information that plaintiffs want is directed at knowledge he obtained and knew about before he was in his current position as CEO.” ([12/22/2020 Tr. 40:4-11](#)). He also granted Plaintiffs “leave to file a motion requesting production of Mr. Chen’s custodial file.” ([ECF 704](#)).

¹ ZHP has indicated that it intends to move for a protective order to block the Plaintiffs’ ordered deposition of Baohua Chen, but in light of the current record described herein, including the testimony of Min Li illustrating Mr. Chen’s central involvement and interaction with all parts of the company, ZHP’s knowing marketing of contaminated valsartan, and Mr. Chen’s dominant role in reacting and responding to the disclosure of the nitrosamine contamination in 2018, such a motion would be frivolous. Moreover, Judge Schneider’s Order required ZHP to “provide a proposed date for Mr. Chen’s deposition in the event ZHP’s motion for protective order is denied.” ([ECF 704](#)). In accordance with this order, ZHP scheduled Mr. Chen’s deposition. During the meet and confer last week, ZHP suggested that Mr. Chen might not be willing or able to leave China to be deposed. Such a failure would be a refusal to provide discovery.

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Mr. Chen's deposition is currently scheduled to begin the evening of May 31, 2021 (this is Memorial Day and Plaintiffs have separately requested that the deposition be rescheduled for later that week or the start of the following week at the latest). ZHP asked Plaintiffs to consent last week to push the deposition of Mr. Chen out weeks to allow them to first move for a protective order in June 2021, and Plaintiffs could not agree in light of the existing Order requiring the motion to be filed and decided in advance, and the need to complete this deposition and the upcoming deadline for Plaintiffs' expert reports.

Along with the record previously established, important revelations during the deposition of Min Li from April 19-21, 2021, firmly establish that the custodial file of Mr. Chen should be compelled now, in time for Plaintiffs to review what is produced. This will give Plaintiffs the necessary time to also evaluate and attempt to remedy the inevitable deficiencies in the production.

Min Li is the Vice President of Analytical Operations of ZHP, and was produced as a 30(b)(6) corporate representative regarding (1) the cause of the nitrosamine contamination, (2) the root cause investigation of the contamination, (3) the chromatography and other testing, and (4) ZHP's knowledge of the health and safety risks related to the contamination. [REDACTED]

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² At the outset of the litigation when ZHP was fighting Plaintiffs' effort to assert personal jurisdiction, Plaintiffs served Jun Du with a Complaint at his New Jersey residence, which put an end to that obstruction of the Plaintiffs' ability to initiate the substantive phase of the litigation against ZHP.

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2. Plaintiffs Additional Discovery Requests from ZHP

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3. Aurobindo Discovery Status and Plaintiffs' Request for Sanctions

A. Plaintiffs' Motion to Strike All of Aurobindo's Defenses

Since Plaintiffs filed their motion on Friday, April 23, 2021 (less than a week ago), Aurobindo has continued to produce documents that are long overdue, further compounding the prejudice on Plaintiffs.

On Saturday, April 24, 2021, the US Aurobindo entities produced an additional 3,436 documents. The production log states that these documents pertain to a number of US custodians, with three deponents whose depositions have already taken place (Prasad Gorijavolu, Bhadrash Doshi, and Blessy Johns) among them. The production further includes documents for one custodian whose depositions are taking place this week (Sandra Martinez). That same day, Aurobindo Pharma Ltd. (the Indian entity) produced 5,474 documents.

On Monday, April 26, 2021, the US Aurobindo entities produced an additional 16,068 pages of documents. Because at the time this agenda letter was finalized, the production has not been loaded by Plaintiffs' vendor, Plaintiffs are not able to provide the document count.)

Plaintiffs were also informed on Monday that Aurobindo Pharma Ltd. would be making a supplemental production on Wednesday. Plaintiffs immediately responded and inquired about the volume of the production, but no response had been provided.

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In light of these ongoing (and very late) productions, Plaintiffs also asked Aurobindo to provide them with a document count for what was still coming. Plaintiffs have not received a response to this either.

All of this only underscores the reasons Plaintiffs' motion was brought.

For this reason, Plaintiffs request the following:

- Plaintiffs ask that Aurobindo not be granted an extension to respond to Plaintiffs' motion;
- Plaintiffs ask that Aurobindo provide the requested information on the record to the Court and to Plaintiffs;

B. Aurobindo's Privilege Logs

1. **Aurobindo's Privilege Log Regarding Documents from ToxRox and Meridan:** These issues have been fully briefed.
2. **Aurobindo's First Privilege Log:** On March 5, 2021, Aurobindo provided Plaintiffs with a privilege log, containing the cast of characters as required by the Court. This log contained 159 entries. The parties have met and conferred on this log numerous times already and have the following remaining disputes:
 - **Improper Work Product Designations:** The March 5, 2021 privilege log contains only three individuals who are lawyers – Tini Thomas, Hunter Murdock, and Faith A. Phillips. The vast majority of the entries (which will be provided) do not contain any lawyer on the communication or as an author of the document. There is also no explanation as to why the purportedly protected documents are entitled to work-product protection when they are authored by and do not involve any attorney. There is no information in the log to determine whether the particular entries were prepared in anticipation of litigation and for no other purpose. *In re Riddell Concussion Reduction Litig.*, 2016 WL 7108455, at * 6 (D.N.J. Dec. 5, 2016) (Schneider, J.). Some entries, such as Auro-MDL 2875-0088941, claim work product protection related to 2006 litigation, with no explanation as to what that litigation was or whether it was in any way related to this one. *See Leonen v. Johns-Manville*, 135 F.R.D. 94, 97 (D.N.J. 1990) (requiring “a close connection in parties or subject matter between . . . two [separate] matters”).
 - **Improper Privilege Designations:** For the same reasons, Aurobindo's privilege designations are improper because they do not provide detail sufficient to determine whether the non-lawyer communications are entitled to attorney-client privilege protection, which is an even higher bar. *SmithKline Beecham Corp. v. Apotex*

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Corp., 232 F.R.D. 467, 482 (E.D. Pa. 2005) (explaining that “if the party invoking the privilege does not provide sufficient detail to demonstrate fulfillment of all the legal requirements for application of the privilege, his claim will be rejected”). Several entries also claim privilege/work-product protection over correspondence that appears to have been sent to whole group email lists and otherwise broadly disseminated, which also requires de-designation. *Id.* at 478.

- There are also a substantial number of entries involving third-parties with no explanation as to why such communication with a third-party should be entitled to privilege or work-product protection.
3. **Aurobindo’s Latest Privilege Log:** On Wednesday, April 21, 2021, Defendants served an updated privilege log. While the previous log contained only 159 entries, this new log contains 3,479. There are many questionable entries in the log, including documents titled “valsartan risk assessment report,” “valsartan risk investigation report,” “risk assessment report,” “out of trend results.pdf,” and “MF 023084 Nitrosamine General Advice Letter.” At this time, Plaintiffs also cannot meaningfully evaluate most of it, because Aurobindo failed to provide a cast of characters (as was previously ordered by the Court). Following Plaintiffs’ email to the Court on Saturday, April 24, 2021, Aurobindo agreed to provide a supplemental log on Tuesday, though at the time Plaintiffs finalized their agenda letter, they had not received it. Unless, Aurobindo substantially amends its log and provides the cast of characters, Plaintiffs anticipate requiring the Court’s guidance during the conference.

C. Aurobindo’s Document Retention and Destruction Policies

Approximately one month ago, the Court ordered Aurobindo to produce its document retention and destruction policies. Plaintiffs have been unable to locate them. Plaintiffs therefore requested that Aurobindo tell Plaintiffs whether these had been produced, and if so, what the Bates numbers were. Plaintiffs have not received a response to this request.

Plaintiffs therefore ask the Court to ask Aurobindo on the record whether these policies have been produced. To the extent they have not been produced, Plaintiffs note that this fact should be yet another reason for which sanctions are warranted. Moreover, Plaintiffs ask that these policies be produced no later than the end of the week.

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4. Hetero Discovery Dispute Status

Despite Hetero's ongoing production of documents and overlays material deficiencies remain, including but limited to continued missing documents and document categories, documents needed for context that are withheld on the basis of non-responsiveness, and documents that are withheld on the basis of privilege that plaintiffs have challenged, some of which Hetero has agreed to produce. These are all documents that are clearly responsive to Plaintiffs' document requests and should have been produced months ago. The first Hetero deposition, which was set to begin last week, was cancelled due to the witness falling ill with COVID. The first Hetero deposition still currently scheduled is set to begin on Thursday. Plaintiffs continue to have significant concerns about the completeness of Hetero's document production, but have been forced to begin depositions given the schedule and time frame for expert reports. Plaintiffs have previously catalogued in detail the numerous deficiencies with Hetero's production since its purported completion in November 2020, and do not repeat them here, but note that they may still require the Court's definitive intervention as depositions begin taking place. The parties are also trying to work through a time scheduling issue with Indian witnesses, but hope to be able to resolve that prior to the conference.

5. Retailer Discovery Status

Per Your Honor's instructions, the parties submitted simultaneous briefing on April 23, 2021 concerning three of Plaintiffs' draft document requests that Retail Pharmacy Defendants do not believe they even need to negotiate, let alone answer, at this time. The parties have been negotiating the remaining requests. It is Plaintiffs' expectation that any lingering disputes on the wording of the other requests will be brought to Your Honor's attention soon.

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6. Wholesaler Discovery Status

Plaintiffs sent Wholesaler Defendants a letter on March 12, 2021, concerning their draft discovery requests. The parties had a meet and confer on April 13, 2021, and pledged to get back with each other after following up internally on separate items. Plaintiffs reverted to Wholesaler Defendants on April 20, but have not heard back from Wholesaler Defendants at all since the April 13 call. While Plaintiffs remain hopeful the parties will resolve disputes amongst themselves, Plaintiffs believe deadlines from Your Honor would be very helpful to speed along this process that has languished since December 2020.

7. Briefing Schedule on Motion to Amend

The Parties met and conferred on the briefing schedule and were unable to reach agreement. Plaintiffs' proposal is as follows:

- 60 Days After Plaintiffs' Motion: Defendants each file briefs no longer than 40 pages in length in size 14 font (consistent with the local rules);
- 60 Days After Defendants' Response: Plaintiffs file responsive briefs no longer than 40 pages in length in size 14 font (consistent with the local rules);

Plaintiffs' proposal differs from Defendants' in two important ways. First, the briefing schedule is longer and allows the parties more time to complete depositions of the API and manufacturer defendants. Second, Plaintiffs have not added a schedule for a sur-reply for Defendants. Defendants' first round of Motions to Dismiss were extensive and resulted in six lengthy orders from the Court. Plaintiffs do not see a reason to put the Court through additional briefing on issues that likely will not be novel.

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8. PFS Deficiency Show Cause Process

Plaintiffs will be prepared to discuss the cases listed in Defendants' letter.

Respectfully,



ADAM M. SLATER